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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/509,391	07/07/2000	JEROEN KRIIGSVELD	702-000648	1936

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EXAMINER

SNEDDEN, SHERIDAN

ART UNIT PAPER NUMBER

1653

DATE MAILED: 03/11/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/509,391

Applicant(s)

KRIJGSVELD ET AL.

Examiner

Sheridan K Snedden

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– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 23 December 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36-61 is/are pending in the application.
- 4a) Of the above claim(s) 39, 41-47 and 58-61 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36-38, 40 and 48-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Applicant's cancellation of claims 1-21 and addition of new claims 22-35 in Paper #13, filed July 7, 2000 is acknowledged. This Office Action is in response to Paper #16, filed December 23, 2002. Claims 22-35 have been canceled.

2. Newly submitted claims 36-61 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Each of peptides described as TC-1, TC-1*, TC-2, TC-1a-d, rMTC-1*, rMTC-2, rYTC-1 and rYNAP are directed to patentably distinct and/or independent peptides. Absent factual statement/evidence to the contrary, each different peptide sequence is considered distinct and/or independent, one from the other on the basis of physical, chemical and biological properties and function(s).

In addition, claims 58-61 add methods for the preparation of a medicament, release systems and microbicidal peptides. Each of these methods are patentably distinct and outside the scope of the original presentation of the claims.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 39, 41-47 and 58-61 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

3. Claims 36-38, 40, 48-57 are under examination.

Withdrawal of Objections and Rejections

4. The objections and/or rejections of Paper #14 are withdrawn as necessitated by Applicant's amendment.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 36-38, 40 and 52-55 are rejected under 35 U.S.C. 102(b) as being anticipated by Daly *et al.* (Patent No: 5,656,724). Daly *et al.* disclose recombinant CXC chemokines whose amino acid sequences, SEQ ID NO: 9 and 10, comprise the exact same amino acid sequence of TC-1, SEQ ID NO: 12, and TC-2, SEQ ID NO: 6 (claims 36-38, 40 and 52-55; note that the optional modifications recited in claim 36 are not considered). In additional, Daly *et al.*, column 1 line 32, disclose these CXC chemokines as small inducible proteins having a specific arrangement of four position-invariant cysteine residues in their primary amino acid sequence that form two disulfide bonds. Thus, the reference anticipates the claimed invention.

7. Applicant's arguments filed December 23, 2002 on pages 10 and 11 have been fully considered but they are not persuasive. Applicant urges that the peptides of TC-1 and TC-2 are not taught by Daly *et al.* This is not found persuasive because the claims recite "comprises at least the amino acid sequence of TC-1." Therefore, whereas Daly *et al.* does not teach TC-1,

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Daly *et al.* teaches a sequence that “comprises at least the amino acid sequence of TC-1” as recited in the claim. Same logic applies to TC-2.

Applicant additionally argues that the absence of residues in TC-1 enhance the activity of TC-1 over the activity of the sequences taught by Daly *et al.* This is not found persuasive because the claims recite “comprises at least the amino acid sequence of TC-1,” and does not provide any limitation with regards to activity. Therefore, whereas Daly *et al.* does not teach TC-1 having enhanced antimicrobial activity, Daly *et al.* teaches a sequence that “comprises at least the amino acid sequence of TC-1” as recited in the claim. Same logic applies to TC-2.

8. Claims 36, 38, and 48-56 are rejected under 35 U.S.C. 102(b) as being anticipated by Baggiolini *et al.* (WO 90/06321). Baggiolini *et al.* teach the administration of daily doses (claim 33) of recombinant CXC chemokine NAP-2 for the treatment of human conditions associated with bacterial and fungal infections (page 9 third paragraph; regarding claims 48-51 and 56). Comparison of the sequences given in figure 1 of the specification show that NAP-2 is 97% identical to TC-1 (SEQ ID NO: 12; regarding claims 52-55). The sequence of NAP-2 differs from the sequence of TC-1 by the presence of 2 additional amino acids on the N-terminus, thus, the sequence of NAP-2 fully comprises the sequence of TC-1, or SEQ ID NO: 12 (regarding claims 36 and 38). Thus, the reference anticipates the claimed invention.

9. Applicant's arguments filed December 23, 2002 on pages 11-12 have been fully considered but they are not persuasive. Applicant argues that the absence of residues in TC-1 result in differences in the structure and activity of the peptide as compared to the sequences

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taught by Baggiolini *et al.* This is not found persuasive because the claims recite “comprises at least the amino acid sequence of TC-1,” and does not provide any limitation with regards to activity or structure. Therefore, whereas Baggiolini *et al.* does not teach TC-1 having enhanced antimicrobial activity or altered structure, Baggiolini *et al.* teaches a sequence that “comprises at least the amino acid sequence of TC-1” as recited in the claim. Same logic applies to TC-2.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 36, 38, and 48-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baggiolini *et al.* (WO 90/06321) in view of Cimbollek *et al.* (1996).

Baggiolini *et al.* teach the administration of daily doses of recombinant CXC chemokine NAP-2 for the treatment of human conditions associated with bacterial and fungal infections (pages 9-10; regarding claims 48-51 and 56). Comparison of the sequences given in figure 1 of the specification show that NAP-2 is 97% identical to TC-1 (SEQ ID NO: 12; regarding claims 52-55). The sequence of NAP-2 differs from the sequence of TC-1 by the presence of 2 additional amino acids on the N-terminus, thus, the sequence of NAP-2 fully comprises the sequence of TC-1, or SEQ ID NO: 12 (regarding claims 36 and 38). Baggiolini *et al.* does not disclose the NAP-2 for the treatment of bacterial and fungal endocarditis.

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Cimbollek *et al.* teach that both fungal and bacterial infections are associated with endocarditis (page 1432, first paragraph; regarding claim 57).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to use the known antimicrobial chemokine, NAP-2, for the treatment of endocarditis caused by fungal and bacterial infection. The person of ordinary skill in the art would have been motivated to treat endocarditis with the above chemokine because the chemokine has known antimicrobial activity. The person of ordinary skill in the art would have expected success because endocarditis is caused by both fungal (claim 34) and bacterial (claim 32) infections (Cimbollek *et al.*). Thus, the claimed invention was within the ordinary skill in the art to make and use at the time it was made and was as a whole, *prima facie* obvious.

12. Applicant's arguments filed December 23, 2002 on page 13 have been fully considered but they are not persuasive. Applicant argues that the absence of residues in TC-1 result in differences in the structure and activity of the peptide as compared to the sequences taught by Baggiolini *et al.* This is not found persuasive because the claims recite "comprises at least the amino acid sequence of TC-1," and does not provide any limitation with regards to activity or structure. Therefore, whereas Baggiolini *et al.* does not teach TC-1 having enhanced antimicrobial activity or altered structure, Baggiolini *et al.* teaches a sequence that "comprises at least the amino acid sequence of TC-1" as recited in the claim. Same logic applies to TC-2.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re*

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Merck & Co., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Taken together, the references indicate the use of NAP-2 for endocarditis caused by bacterial and fungal infections.

Claim Rejections - 35 USC § 112

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 37, 40 and 52-55 are indefinite, as they do not further limit the parent claim.

Claims 37, 40 and 52-55 recite the limitations of percent homology or further modifications of the peptide of SEQ ID NO: 12 outside the scope of claim 36 from which they depend. Claim 36 recites a peptide that comprises at least the amino acid sequence of SEQ ID NO: 12 and provides no antecedent basis for limitations in the claims that would modify SEQ ID NO: 12.

Conclusion

14. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

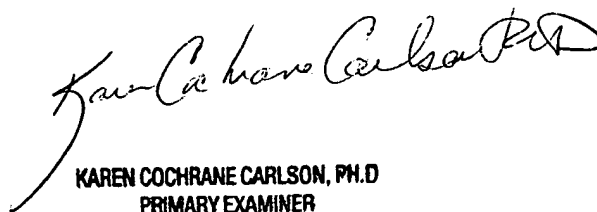
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan K Snedden whose telephone number is (703) 305-4843. The examiner can normally be reached on Monday - Friday, 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone number for regular communications to the organization where this application or proceeding is assigned is (703) 746-3975.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SKS
March 7, 2003

SKS


KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER